JUL 23 2009

510(K) SUMMARY

Solo™ Insulin Patch Pump
510(k) Number K090245

Date Prepared: July 21, 2009.

Applicant's Name:

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Contact Person:

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Trade Name:

Solo™ Insulin Patch Pump

Classification Name:

Insulin infusion pump

Classification:

Regulation # (21 CFR 880.5725), FDA has classified insulin infusion pumps as class II devices (product code LZG) and they are reviewed by the General Hospital panel.

Predicate Devices:

- iXL Diabetes Management System (Insulet Corp.), product code LZG, cleared for marketing under K031373, K042792

- Paradigm Model 515 (Medtronic Minimed), product code LZG, cleared for marketing under K073356.

Intended Use:

The Solo™ Insulin Patch Pump is intended for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Device Description:

The Solo™ Insulin Patch Pump (Solo™) is a miniature, portable programmable insulin pump, which adheres to the patient's skin. The patch is comprised of two connected parts: a disposable reservoir, in which the insulin is stored and a reusable pump, which includes the pumping mechanism and electronic components. The patch is controlled via a remote control unit.

The Solo™ Insulin Patch Pump is designed to deliver basal and bolus insulin doses at various rates, volumes and patterns, as prescribed by the user's physician, and includes the features available in the predicate devices.

Technological Characteristics:

The Solo™ Insulin Patch Pump's technological characteristics are the same as those of its predicate devices. Same as its predicates, Solo™ is an external, portable insulin infusion pump controlled by a hand-held controller. Same as Insulet's OmniPod, Solo™ communication is by means of radio frequency.

Same as OmniPod, the Solo™ insulin dispensing patch is worn on the user's skin. Same as Minimed's Paradigm, the Solo™ has a modular design which enables disconnection and reconnection of the insulin dispensing unit from the cannula at the user's discretion.

Sterilization method and use lifetime of the sterile parts is identical to the predicate devices.

Solo™ includes the same functions, mechanical and software safety features, and alarms and alerts as the predicate devices.

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Performance Tests:

Solo™ accuracy and In-house functional performance testing of Solo™ was conducted in Medingo according to a verification and validation plan based on risk analysis, literature search and requirements of applicable standards.

The following studies were conducted in certified contract laboratories: Biocompatibility, Insulin Compatibility, microbial ingress, cleaning and disinfection verification, Shelf life, Electrical Safety, Environmental, EMC and RF Compatibility. Software validation was performed in Medingo by an external software QA contractor.

Solo™ and its components successfully passed all performance evaluations according to its performance criteria.

Conclusion:

Medingo believes that, based on the information provided in this submission, the Solo™ Insulin Patch Pump is substantially equivalent to its predicate devices without raising any new safety or effectiveness issues.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Arava Hacohen
Vice President Quality and Regulatory Affairs
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Re: K090245
Trade/Device Name: Solo™ Insulin Patch Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: July 8, 2009
Received: July 15, 2009

Dear Ms. Hacohen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K090245

Device Name:

Solo™ Insulin Patch Pump

Indications for Use:

The Solo™ Insulin Patch Pump is intended for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

The Solo™ Insulin Patch Pump is for prescription use only.

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Prescription Use ___√___ OR Over the Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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